

REMARKS

Claims 43, 46-48, 50, 52-55, 57-60 are pending in this application. As to Claims 57-60 added above, see Applicants' specification at, e.g., page 1, line 14; the paragraph bridging pages 11-12; paragraph bridging pages 13-14; page 14, line 5; sentence bridging pages 15-16; last line on page 19; page 20, line 2; page 27, first line under table; page 28, lines 10, 14; etc. Claims 43, 50 are amended above as to dependency. Claims 46, 47, 48, 52, 53, 54, 55 are amended above to conform to their base claims. The claim amendments have been made and the new claims added for simplifying this application and without prejudice to presentation of the claims prior to amendment in another application such as a continuation application.

From the advisory action, it is applicant's understanding that Claims 43, 46-48, 50, and 53-55 continue to stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam or Volicer, in view of McNally; that Claim 52 continues to stand rejected under 35 U.S.C. 103(a) based on a combination of Mechoulam or Volicer with two other references, McNally and Pars; and that Claims 43, 46-48, 50, and 52-55 continue stand rejected under 35 U.S.C. 103(a) based on a combination of Pars and McNally.

Applicants respond as follows. The dependency of the rejected claims has been changed to depend on new claim 57 which recites: "An aerosol-dispensable pharmaceutical composition comprising: tetrahydrocannabinol and hydrofluoroalkane, wherein the composition is aerosol-dispensable."

The Examiner in the advisory action cites col. 5, lines 33-35 of Mechoulam as teaching and/or reasonably suggesting THC aerosol formulations. Applicant disagrees that col. 5, lines 33-35 of Mechoulam relates in any way to an aerosol; Applicant sees col. 6, lines 47-49 of Mechoulam which the Examiner has not mentioned but states: "In addition, the compositions of the present invention may be formed as aerosol, for intranasal and like administration." Turning to Volicer at col. 4, the part that the Examiner cites states: "Suitable specific forms of administration include the forms for the oral route, buccal and sublingual forms of administration, subcutaneous, transdermal, intramuscular or intravenous forms of administration and rectal forms of administration, as well as

forms for inhalation.” The part of Volicer at col. 5 that the Examiner cites states: “Dronabinol, alone or in combination with other suitable components, can be made into aerosol formulations to be administered via inhalation. These aerosol formulations can be placed into pressurized acceptable propellants, such as dichlorodifluoromethane, propane, nitrogen, and the like.”

The Examiner has cited Mechoulam or Volicer as the closest art, but neither Mechoulam nor Volicer teaches how to make an aerosol-dispensable THC pharmaceutical composition, and how to make an aerosol-dispensable THC pharmaceutical composition was not yet known in the art. THC is a high dose, non-volatile drug.¹ Despite the fact that the interest in pharmaceutical THC dates back nearly thirty years when efforts were focused on developing a CFC propellant MDI to deliver THC to the lungs for treating asthma, no acceptable delivery systems of inhalation THC had been developed before this invention.² Volicer’s statement that “These aerosol formulations can be placed into pressurized acceptable propellants, such as dichlorodifluoromethane, propane, nitrogen, and the like” would be viewed by a person of ordinary skill in the art as merely a hopeful hypothesis on Volicer’s part for which there was no scientific support either in Volicer or in the scientific literature generally. Mechoulam and Volicer clearly fail to contain an enabling disclosure of an aerosol-dispensable THC composition. Applicant has provided sufficient facts to rebut any initial presumption of operability that Mechoulam or Volicer may have enjoyed when first cited by the examiner.

Wherefore, reconsideration and withdrawal of the art rejections are respectfully requested.

In view of the foregoing, it is respectfully requested that the application be reconsidered, that claims 43, 46-48, 50, 52-55, 57-59 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephone or personal interview.

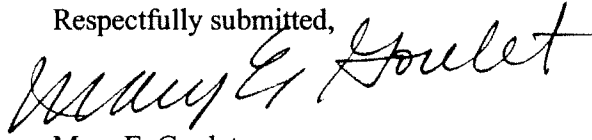
A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any

¹Weers 1.132 Declaration (executed March 27, 2006), page 5, paragraph 7.

²Weers 1.132 Declaration (executed March 27, 2006), paragraph 9 bridging pages 8-9.

deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,

A handwritten signature in cursive script, reading "Mary E. Goulet". The signature is written in black ink and is positioned above the printed name and registration number.

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